

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FILED
IN CLERKS OFFICE
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U.S. DISTRICT COURT
DISTRICT OF MASS.

THE UNITED STATES OF AMERICA ex rel.
BLAIR COLLINS, and

THE STATES OF CALIFORNIA, DELAWARE,
FLORIDA, GEORGIA, HAWAII, ILLINOIS,
INDIANA, LOUISIANA, MICHIGAN, NEVADA,
NEW HAMPSHIRE, NEW MEXICO, NEW
YORK, TENNESSEE, and TEXAS, ex rel. BLAIR
COLLINS,

THE COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA ex rel.
BLAIR COLLINS, and

THE DISTRICT OF COLUMBIA, ex rel. BLAIR
COLLINS,

Plaintiffs,

v.

PFIZER INC.,

Defendant.

CIVIL ACTION NO.

04-11780 DPW

*FILED IN CAMERA
and UNDER SEAL*

RESTATED AND AMENDED
FALSE CLAIMS ACT
COMPLAINT

I. INTRODUCTORY STATEMENT

The Plaintiff, BLAIR COLLINS, by and through his counsel of record, brings this action on behalf of the United States of America against PFIZER INC. (the "Defendant") pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA"), and on behalf of the above named States under their respective State False Claims Acts ("State FCAs") (together referred to herein as "*Qui Tam* Action"). Pursuant to 31 U.S.C. § 3730 (b)(2), and comparable provisions in State FCAs, this action is brought *in camera* and under seal. Plaintiff Blair Collins also brings this action on his own behalf under the FCA,

31 U.S.C. section 3730(h), seeking redress for Defendant's wrongful and unlawful retaliation and termination of his employment.

Plaintiff alleges that Defendant PFIZER INC. has violated numerous laws, including the Federal and State FCAs, the Federal Food, Drug, and Cosmetic Act and the Medicare-Medicaid Anti-Kickback Act (and comparable state laws), and has violated the terms of two Corporate Integrity Agreements between it and the government, by engaging in unlawful promotional and pricing activities in the marketing of numerous drugs manufactured and/or sold by Defendant from at least 1998 to at least 2005. Pfizer's actions and omissions have caused physicians to prescribe and administer such drugs to their patients over competitor's drugs, have caused Pfizer's drugs to be listed on formularies over competitor's drugs, have caused Pfizer's more expensive brand name drugs to be prescribed and listed on formularies in lieu of less expensive generic drugs, have caused physicians to prescribe Pfizer's drugs for "off-label" purposes, and at dosages that are unnecessary and adversely affect patient quality of care, and have caused Government Health Care Programs to receive and pay false or fraudulent bills submitted to such programs, and to pay higher prices and to receive lower rebates for such drugs.

Plaintiff/Relator further alleges that Defendant PFIZER INC. has violated the whistleblower's protection section of the FCA, 31 U.S.C. section 3730(h), by subjecting him to adverse actions and ultimately terminating plaintiff's employment in retaliation for his attempts to report and correct the illegal conduct described herein.

Pfizer's illegal activities are each violations of law, but together demonstrate a concerted and well-organized national corporate strategy to use kickbacks, off-label promotion, pricing "incentives" and other illegal tactics directed from the highest levels of the company to assure that Pfizer's drugs would not only compete, but would receive preferential treatment, thereby

putting Pfizer's competitors at an unfair disadvantage, depriving certain providers and consumers of a fair and informed choice, and causing Government Health Care Programs (as defined below) to expend excessive amounts of money to reimburse the cost of Pfizer's drugs. All of this has been done despite two Corporate Integrity Agreements, the Department of Health and Human Services Office of Inspector General's Guidelines, and internal complaints from employees such as Relator who instead of being treated with respect, are unfairly and illegally retaliated against.

II. JURISDICTION AND VENUE

1. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. § 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730, and has supplemental jurisdiction over the State FCA claims pursuant to 31 U.S.C. section 3732(b) and 28 U.S.C. § 1367.

2. Venue is appropriate as to the Defendant in that PFIZER INC. can be found in, resides in, and/or transacts business in this judicial district. Therefore, within the meaning of 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a), venue is proper.

3. To Relator's knowledge, jurisdiction over this action is not barred by 31 U.S.C. Section 3730(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party; there has been no "public disclosure" of these allegations or transactions; and, in any event, Relator is the "original source" of the information on which these allegations are based.

III. THE PARTIES

4. Plaintiff Blair Collins is a citizen of the United States of America and a resident of Utah. From October 1998 until August 2003, he was employed by Defendant PFIZER INC. He brings this *Qui Tam* Action based upon direct, independent and unique information obtained during the period of his employment as a pharmaceutical sales representative for the Defendant.

As characterized by the Federal False Claims Act, Plaintiff will often be referred to as “Relator” hereafter. Mr. Collins has made several disclosures to the government regarding the allegations and information in his original Complaint and in this Restated and Amended Complaint, and will be providing the government plaintiffs with further disclosures as well.

5. Defendant PFIZER INC. (“PFIZER”), a publicly-traded corporation, is one of the world’s largest drug companies. It develops, manufactures and markets a wide array of top selling prescription drugs including, for example, LIPITOR, VIAGRA, NORVASC, CADUET, ZYRTEC, ZITHROMAX, ZOLOFT, GLUCOTROL XL, CELEBREX, ARICEPT, DIFLUCAN (and the new version, VIRACEPT), RELPZX, DETROL LA, and NEURONTIN. Pfizer is incorporated in Delaware, and headquartered in New York, New York. It has operations in the United States and several other countries, and maintains its principal place of business in the United States at 232 East 42nd Street, New York, New York. Pfizer conducts business in the Commonwealth of Massachusetts and every state within the United States. In 2003, the year Relator’s Complaint was filed, Pfizer had revenues of some \$45.2 billion and 122,000 employees around the world; in the most recent past year (2006), Pfizer’s revenues topped \$52.5 billion dollars.

IV. FEDERAL AND STATE HEALTH INSURANCE PROGRAMS

6. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 *et seq.*, (hereinafter “Medicare”) is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services through its Centers for Medicare and Medicaid Services (“CMS”). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons

over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, including under Part D of the Medicare Program, the Medicare Prescription Drug Benefit effective in about January 2004.

7. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§. 1396-1396v (hereafter “Medicaid”), is a Health Insurance Program administered by the Government of the United States and the various individual States (and territories) and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services through CMS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid. States also use taxpayer revenue to fund other health insurance programs for children and/or adults, including, for example, the so-called S-CHIPS program, see 42 U.S.C. section 1397dd(a)-(c), and in Massachusetts the so-called Uncompensated Care Pool.

8. The Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS”) (now known as “TRICARE”), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

9. The federal government, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non profit disproportionate share hospitals (“DSH”). *See generally* 38 U.S.C. § 8126; 42 U.S.C. § 256b.

10. The Federal Employees Health Benefits Program (“FEHBP”) provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described in paragraphs 6-10 shall be referred to as “Government Health Care Programs”).

V. RELEVANT FEDERAL AND STATE LAWS

A. The Federal Food, Drug and Cosmetic Act

11. The Federal Food, Drug and Cosmetic Act (“FFDCA”) prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration (“FDA”) has determined that the drug is safe *and* effective for its intended use. 21 U.S.C. § 355 (a) and (d). An approved drug may be prescribed by doctors for uses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or “off-label” uses. 21 U.S.C. § 331(d). If the manufacturer intends to promote the drug for a new unapproved use, the drug must be resubmitted to the FDA for testing and

approval (or the manufacturer must obtain an exemption therefrom) and the promotional materials must meet certain statutory requirements. 21 U.S.C. § 360aaa, *et seq.*

12. Whether a drug is FDA-approved for a particular use is a key factor in whether a prescription of the drug is reimbursed under Government Health Care Programs. For example, reimbursement under Medicaid is, in most circumstances, available only for “covered outpatient drugs.” 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are “used for a medical indication which is not a medically accepted indication.” *Id.* §1396r-8(k)(3). A medically accepted indication includes a use “which is approved under the Federal Food Drug and Cosmetic Act” or which is included in a specified drug compendia. *Id.* §1396r-8(k)(6). There is a single exception: in certain circumstances Medicaid will reimburse the prescription of certain single-source or multi-source innovator drugs for an “off-label” use where the individual State has determined, *inter alia*, that the drug is essential to the health of beneficiaries. 42 U.S.C. § 1396r8(a)(3).

13. The Federal Food, Drug, and Cosmetic Act also prohibits, and provides criminal penalties for, the dissemination of certain written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug that is not described in the FDA approved labeling of the drug. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa(b) which include:

- (1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) or section 355 of this title or a biologics license issued under section 262 of Title 42;
- (2) the information meets the requirements of section 360aaa-1 of this title;
- (3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it were derived from research conducted by another

manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary-
(A) a copy of the information to be disseminated; and

(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

(5) the manufacturer has complied with the requirements of section 360aaa-3 of this title (relating to a supplemental application for such use);

(6) the manufacturer includes along with the information to be disseminated under this subsection –

(A) a prominently displayed statement that discloses –

(i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;

(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

(iv) the official labeling for the drug or device and all updates with respect to the labeling;

(v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1) of this section; and

(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

In addition, a manufacturer may disseminate written information on a new use of a drug only if the information is about a clinical investigation with respect to the drug and is contained in an article published in a scientific or medical journal, which is peer-reviewed by experts, or in a reference publication. 21 U.S.C. §360aaa-1 states in part:

(a) Authorized information – A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information –

(1) is in the form of an unabridged –

(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which were published in a scientific or medical journal (as defined in section 360aaa-5(5) of this title), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

(B) reference publication, described in subsection (b) of this section that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation

14. The FFDCA and its implementing regulations further treat drug “price lists” as “labeling” subject to FDA restrictions. *See* 21 U.S.C. § 321(k) and (m); 21 C.F.R. § 202.1(l)(2). These restrictions require price lists to conform to the regulations on labeling, *see* 21 C.F.R. § 201.100(d), or else fit within certain exemptions therefrom, *see* 21 C.F.R. § 200.200 and 201.100(f). It is therefore illegal for a drug manufacturer to market a drug using a price list which does not meet these requirements.

B. Federal and State False Claims Acts

15. The Federal FCA, 31 U.S.C. § 3729(a)(1) makes “knowingly” presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per claim (\$5,500 and \$11,000 for claims made on or after September 29, 1999).

16. The Federal FCA, 31 U.S.C. § 3729(a)(2) makes “knowingly” making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of

between \$5,000 and \$10,000 per claim (\$5,500 and \$11,000 for claims made on or after September 29, 1999).

17. The Federal FCA, 31 U.S.C. sec. 3729(a)(3) makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per claim (\$5,500 and \$11,000 for claims made on or after September 29, 1999).

18. The Federal FCA, 31 U.S.C. § 3729(a)(7) makes it illegal for any person to “knowingly” make, use or cause to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,000 and \$10,000 per claim (\$5,500 and \$11,000 for claims made on or after September 29, 1999).

19. The Federal FCA defines a “claim” to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

20. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov’t Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Georgia State False Medicaid Claims Act,

49 Ga. Code Ann. Chapter 4 at 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*, New Hampshire False Claims Act, N.H. RSA §§ 167:61-b, *et seq.*, New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468), New York False Claims Act 2007, New York Laws 58, section 39, article 13, section 189 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

C. Federal and State Anti-Kickback Laws

21. The Medicare Medicaid Anti-Kickback Act ("AKA"), 42 U.S.C. §1320a-7b (b), makes it illegal to offer, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Government Health Care Program. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient

having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services. Many States have similar laws pertaining to the Medicaid Program.

VI. FACTS AND ALLEGATIONS

A. Defendant Pfizer's Drugs and Sales

22. At all or some of the times relevant to this action, Pfizer manufactured, marketed and/or sold numerous brand name prescription drugs, including those with the trademark names of LIPITOR, VIAGRA, NORVASC, ZYRTEC, ZITHROMAX, ZOLOFT, GLUCOTROL XL, and CADUET ("the Drugs"). At various times relevant to this action, the Drugs were approved by the Food and Drug Administration for certain indications as described below.

(a) **LIPITOR** (atorvastatin calcium). LIPITOR was originally manufactured by Warner Lambert Company ("WL") and co-marketed by WL and Pfizer from 1997-2000 when WL, and its subsidiary Parke-Davis, were acquired by Pfizer. LIPITOR was first approved to reduce elevated total cholesterol, low density lipids (LDL) and triglyceride levels in patients with primary hypercholesterolemia (i.e. elevated cholesterol levels). When introduced into the market in 1997, LIPITOR faced several competitors, including two, Zocor (manufactured by Merck) and Pravachol (manufactured by Bristol Myers Squibb) which had broader approved indications (i.e. to reduce fatal and non-fatal strokes and heart attacks) than LIPITOR. Nevertheless, by April 2000, LIPITOR was the number one prescribed cholesterol lowering medication and indeed the number one selling brand name drug in the United States.

It was not until late July 2005, that LIPITOR was granted approved for any additional indications, at that time for the reduction of cardiovascular events (heart attacks and strokes), but *only in* patients with coexisting elevated cholesterol levels *and* hypertension (i.e. high blood pressure).

In March 2007, the FDA approved additional indications for LIPITOR, in specific: (1) reducing the risk of nonfatal Myocardial Infarction; (2) reducing the risk for fatal and non-fatal strokes; (3) for use during certain types of heart surgery (or in lieu thereof); (4) reducing the risk of hospitalization for heart failure (congestive heart failure; and (5) to reduce chest pain in patients with heart disease.

Notably, LIPITOR *has not been approved* to reduce fatal and non-fatal strokes or heart attacks in patients with diabetes or atherosclerosis.

(b) **VIAGRA (sildenafil citrate)**, created by Pfizer, was launched and sold by Pfizer beginning in April 1998. It was approved for the treatment of erectile dysfunction and to date is not approved for any other indication.

(c) **NORVASC (amlodipine besylate)**, a calcium channel blocker, was created and manufactured by Pfizer. It was originally launched in 1991 and replaced Pfizer's earlier blockbuster blood pressure lowering medication called Procardia XL. NORVASC quickly became the dominant blood pressure medication in a market with some 50 competitors. At all relevant times, NORVASC was approved for the treatment of hypertension, chronic stable angina and vasospastic angina. NORVASC is not approved to treat coronary artery disease ("CAD"), although Pfizer details it for that use and even promotes it for that use on the

company's web site.

(d) **ZYRTEC (cetirizine hydrochloride)** was created by UCB Pharma and was sold by Pfizer starting in 1996. This drug was first approved for treatment of seasonal and perennial allergic rhinitis and for certain skin allergies in adults, and was later approved for use in children. It carries a post-marketing adverse events warning in its label/package insert, including for suicide and suicidal ideation.

(e) **ZITHROMAX (azithromycin)** was launched and sold by Pfizer beginning in 1991. It is an antibiotic which was at all relevant times approved/indicated for the treatment of patients with certain enumerated mild to moderate infections/disease states caused by certain susceptible strains of microorganisms (i.e. bacteria);

(f) **ZOLOFT (sertraline hydrochloride)** was also launched and sold by Pfizer in 1991. It is indicated for the treatment of *adults* with depression, obsessions and compulsions, and panic disorder (with or without agoraphobia). Zoloft's *only approved use in children* is for the treatment of obsessions and compulsions.

(g) **GLUCOTROL and GLUCOTROL XL (glipizide)** was launched and sold by Pfizer starting in 1984. Its delivery system was changed in 1990 to the XL formulation and delivered through the gastro-intestinal therapeutic system ("GITS") by way of extended release tablets. The drug is indicated as an adjunct to diet for the control of hyperglycemia and its associated symptomatology in patients with non-insulin dependent diabetes mellitus (i.e. Type 2 diabetes).

(h) **CADUET** is a single/fixed dose pill prescription drug consisting of 10 mg. of LIPITOR (the leading branded prescription drug for lowering cholesterol) and 5 mg. of

NORVASC (the leading branded prescription drug for high blood pressure). It was approved by the FDA on January 30, 2004 for the reduction of cholesterol and high blood pressure, and launched by Pfizer in May 2004. CADUET effectively extended the patent protection of both NORVASC and LIPITOR (which would face generic competition when their patent protection expired). CADUET is indicated for patients for whom *both* LIPITOR and NORVASC are approved/indicated. CADUET does not compete head to head with any other drug. Rather, its competitors are those drugs that compete individually against LIPITOR and NORVASC.

23. Each of the Drugs is or is among the top sellers in its field (or in the United States), and generates large revenues for Pfizer. For example, PFIZER'S approximate revenues from United States' sales of LIPITOR were \$7.6 billion in 2003, \$8.6 billion in 2004, \$9.2 billion in 2005, and \$10.3 billion in 2006. By way of comparison, for 2003 United States sales: for NORVASC were \$2.2 billion; for ZYRTEC were \$1.05 billion; for ZITHROMAX were \$1.05 billion; for VIAGRA were \$1.4 billion; for ZOLOFT were \$2.3 billion; and for GLUCOTROL XL were \$530 million. Each of the Drugs is not only included, but is a "preferred" drug (i.e. physicians are encouraged or required by the health plans to write prescriptions for these drugs over competing drugs in their class unless there is a generic version of the drug) on many, if not most, private insurance formularies, and has a preferred status as well for Medicaid, Department of Defense and Veteran's Administration Health Plans and, on information and belief, on federal and state employees health benefit plans, and under Medicare Part D.

24. In addition to the above enumerated Drugs, Pfizer has at all relevant times sold numerous other brand name instruction drugs implicated by this Complaint and the allegations

herein, including without limitation, Diflucan, Aricept, Trovan, Celebrex, Bextra, Viracept, Relpax and Detrol LA among others.

B. Pfizer's Corporate Structure

25. At all times relevant to this case, Pfizer marketed its drugs in the United States through U.S. Pharmaceuticals. During Relator's tenure with Pfizer, U.S. Pharmaceuticals was organized through two "Clusters": "Cluster X" which emphasizes cardiovascular drugs and includes all of the Drug described in paragraph 22 above, except for Zoloft; and "Cluster A" which emphasizes central nervous system drugs, including Zoloft. Each Cluster was headed by a Senior Vice President of Sales, and in turn had several Sales Divisions across 8 Regions of the country. Each Region had a Regional Manager, and within each Region there were twelve districts, each with a District Manager and nine or ten sales representatives, including specialty representatives such as IHR's (institutional healthcare representatives), CHSRs (cardiovascular healthcare representatives), and RHRs (renal/urology healthcare representatives).

26. The drugs at issue in this action were in all cases marketed/sold by more than one division within a Cluster, depending on, for example, the specialty of the physician customer or institution, and sometimes were even sold across a Cluster. For example, LIPITOR, NORVASC, and VIAGRA were sold by every sales division in Cluster X, while ZOLOFT was sold by every sales division within Cluster A. Pfizer labeled this corporate approach to marketing "copromotion." According to Pfizer, copromotion enhanced the quality of detailing minutes in physicians' offices and increased the writing of prescriptions. Copromotion ensured that every doctor was called on at least once per week by both a Cluster X representative and a Cluster A representative, and that the high writers and key influencers would be called on at least 2-3 times per week.

27. Pfizer has over the years acquired various other drug companies and their products. Most notably, in June 2000, Pfizer acquired competitor Warner-Lambert Co. and its subsidiary Parke-Davis Labs, and in April 2003, Pfizer acquired competitor, Pharmacia.

C. Pfizer's 2002 LIPITOR Settlement and Corporate Integrity Agreement

28. In late October 2002 Pfizer and its subsidiaries, Warner-Lambert and Parke-Davis, agreed to pay \$49 million to settle allegations that the company violated the False Claims Act, by fraudulently avoiding paying fully the rebates owed to the state and federal governments under the national drug Medicaid Rebate program for the cholesterol-lowering drug LIPITOR. Defendant, Parke-Davis Labs, then a subsidiary of Warner-Lambert, which was subsequently acquired by Pfizer in 2000, allegedly overstated the LIPITOR best price in the first and second quarters of 1999 by concealing \$250,000 of cash discounts that were given to a key managed care customer in Louisiana in exchange for favorable status on the managed care organization's drug formulary. These unreported discounts to the managed care organization allowed Parke-Davis/Warner-Lambert unlawfully to retain over \$20 million in Medicaid Rebates. In addition to the \$49 million settlement, Pfizer entered into a five-year corporate integrity agreement with the United States Department of Health and Human Services' ("HHS") Office of Inspector General ("OIG"). The Corporate Integrity Agreement ("CIA") included requirements that Pfizer certify its best price processes and maintain internal procedures designed to prevent future problems in compliance with the Medicaid program.

29. In response to the LIPITOR settlement, Pfizer stated: "Pfizer acquired Warner-Lambert in June 2000, after the transactions at issue...In addition, Pfizer has entered into a corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which is consistent with Pfizer's existing voluntary compliance

program. .. ‘We are pleased to bring this legacy Warner-Lambert matter to a conclusion,’ said Jeffrey B. Kindler, Senior Vice President and General Counsel of Pfizer.’ In addition, because integrity is one of Pfizer’s core values, we look forward to working with the HHS Inspector General on continuously improving our compliance programs.”

30. Prior to this, in August 2002, Pfizer had sent out new directives to its entire U.S. sales force, including Relator/Plaintiff Mr. Collins, regarding each employee’s duty to report any illegal conduct within the company immediately upon discovery under a so-called “Open Door Policy.” Pfizer’s “Open Door Policy” states, in relevant part: “Freedom from retaliation. The Open Door Policy expressly prohibits any type of retaliation as a result of raising an issue or being involved in the open door process. If a colleague feels that he or she has experienced retaliation, he or she should contact the person responsible for the fact-finding investigation, local Human Resources or Global Diversity.”

31. As detailed below, during 2003, Mr. Collins, in accordance with this Pfizer Open Door Policy and the requirements of the Pfizer LIPITOR Corporate Integrity Agreement, brought to the attention first of his District Manager and then to Corporate Compliance in New York, New York, illegal conduct that was occurring in the Utah District, the Rocky Mountain Region, and elsewhere among the Pfizer sales force. Contrary to assurances provided to employees and the government on paper, Mr. Collins was met with harsh retaliation and then firing in August 2003, despite his stellar record as a Pfizer employee.

D. Pfizer’s Internal Healthcare Law Compliance Program and its Key Principles Guide

32. In the latter part of 2002, Pfizer also began sending to the field sales force various communications relating to compliance with federal laws as part of its new “Healthcare Law Compliance Program.” In January 2003, Hank McKinnel, the CEO of Pfizer distributed Pfizer’s

Key Principles Guide accompanied by a cover letter acknowledging important new compliance initiatives such as the PhRMA Code and Draft Compliance Guidelines by the HHS OIG. The *Key Principles Guide* contains, *inter alia*, acknowledgment of laws prohibiting kickbacks and off-label marketing, and regulating sampling and other actions which may affect government health care drug pricing programs (including the Medicaid rebate program). The CEO promised that more detailed rules and regulations manuals would be coming and that the field sales force, marketing and medical would all be trained in compliance. Relator received these materials and training.

E. Pharma Guidelines Issued in 2003 by the HHS OIG

33. In May 2003, the Inspector General of HHS published final guidance on marketing practices known as the “OIG Compliance Program Guidance for Pharmaceutical Manufacturers” 68 Fed. Reg. 23731 (May 5, 2003) (the “OIG Guidelines” or “Pharma Guidelines”). In addition to addressing kickbacks and other illegal activities, the OIG Guidelines address appropriate Compliance Programs that Pharmaceutical Manufacturers are encouraged to maintain. Some of the relevant elements of those Guidelines are the following:

“Compliance Program Elements II A 2:

The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation..

Designation of a Compliance Officer II C 1:

Responsibilities shall include.... Participating with the company’s counsel in the appropriate reporting of any self-discovered violations of federal health care program

requirements....

II C 2 – Hotlines and Other Forms of Communication

.... Reported matters that suggest substantial violations of compliance policies or applicable federal health care program requirements should be documented and investigated promptly to determine their veracity and the scope and cause of any underlying problem. **The compliance officer should maintain a detailed log that records such reports, including the nature of any such investigation, its results and any remedial or disciplinary action taken. Such information redacted of individual identifiers, should be summarized and included in all reports to the board of directors, the president or CEO, and the compliance committee.”** (emphasis added).

F. Pfizer’s 2004 Neurontin Settlement and Second Corporate Integrity Agreement

34. During the time Mr. Collins was complaining internally at Pfizer, the company was involved in an ongoing federal and state investigation and litigation involving the marketing of Neurontin under Pfizer’s subsidiary Warner-Lambert (before Pfizer’s acquisition of that company), and, on information and belief, was negotiating a possible resolution with the federal and state governments. Subsequently, in May, 2004, Warner-Lambert/Parke Davis/ Pfizer, the United States and the States, resolved the Neurontin investigation by agreeing: (a) that Warner-Lambert would plead guilty in the District of Massachusetts to two counts of violating the Federal Food, Drug and Cosmetic Act and pay a fine of \$240 million; (b) that Warner-Lambert would settle federal and State FCA and consumer protection claims by paying the United States and the States a total of \$190 million to account for damages caused to federal and state health insurance programs; and (c) that Pfizer, Warner-Lambert’s parent company, would enter into a corporate compliance agreement/program to ensure that the changes Pfizer supposedly made

after acquiring Warner-Lambert would be effective in training and supervising its marketing and sales staff and to ensure that any future off-label marketing conduct would be detected and corrected on a timely basis. This Corporate Integrity Agreement (“CIA”) incorporated and superceded the CIA entered into by Pfizer as part of the 2002 LIPITOR settlement referenced above.

The CIA contains several relevant provisions, among them the following:

III A - Duties of the Compliance Officer –

The Compliance Officer is responsible for the day-to-day monitoring and reporting of compliance activities.

III B – Written Standards

Pfizer’s Code of Conduct manual shall set forth the right of individuals to use the Disclosure Program (III E below) and Pfizer’s **commitment to nonretaliation** and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

III E – Disclosure Program –

The Disclosure Program [implemented as the Open Door Policy] shall emphasize a nonretribution and nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained.

The Compliance Officer is required to maintain a Disclosure Log which shall contain a summary of each disclosure received the status of the respective internal reviews and any corrective action taken in response. The Log shall be made **available to the OIG upon request.**

V C – Certifications

The Annual Report shall include a **certification by the Compliance Officer** that, to the best of their knowledge, Pfizer is in compliance with the requirements of the CIA.

VIII – Documents and Record Retention

Pfizer shall maintain for inspection documents and records relating to compliance with the CIA for six years. (Emphasis added)

35. In response to the Neurontin settlement, Pfizer issued a statement that: “The underlying allegations and related investigations originated in 1996, well before Pfizer’s acquisition of Warner-Lambert in 2000. The allegations and conduct pertain solely to Warner-

Lambert practices. Pfizer has cooperated fully with the government to resolve this matter, which did not involve Pfizer practices or employees. Pfizer is committed to compliance with all healthcare laws and FDA requirements and to high ethical standards in all aspects of its business practices. Indeed, the government has acknowledged the voluntary compliance measures Pfizer has long had in place.” (emphasis in original).

G. Plaintiff/Relator’s Position With Pfizer U.S. Pharmaceuticals

36. Plaintiff/Relator Blair Collins began working for Pfizer U.S. Pharmaceuticals, in October 1998 in the Fort Worth, Texas district of the then Southwest Region (renamed the Gulf Coast Region in April, 2003 after Pfizer acquired Pharmacia and realigned Pfizer’s sales divisions). At the beginning of his employment in 1998, Relator worked in a newly formed division called Division J (renamed the Steere Division in early 1999). Relator’s district manager was Dennis Gooch and his Regional Manager was Craig Smith. The Southwest Region at that time included Texas, Louisiana, New Mexico, Arizona, Oklahoma, Utah, Wyoming, Montana and Idaho. The Steere Division was primarily responsible for selling VIAGRA, but the sales representatives also sold other drugs including ZITHROMAX, GLUCOTROL XL, NORVASC (starting late in 1999), and LIPITOR (starting in 2000). They also worked alongside sales reps who were selling ZOLOFT, ZYRTEC, DIFLUCAN, ARICEPT, TROVAN, CELEBREX and BEXTRA, among others. This organizational structure, with multiple reps selling the same product across divisions or groups, was part of Pfizer’s copromotion marketing strategy noted above.

37. For the years 1999 and 2000, Relator was his District’s recipient of Pfizer’s Blue-Vase award given to one individual each year. That person is chosen by their peers as the person who best represents the “Billy Peck” attitude (it shall be done) and the Pfizer core values (among

them are integrity, leadership, performance, teamwork, and loyalty). After his promotion in 2001, Relator was no longer eligible for this award.

38. In about October 2000, Relator's District Manager in Texas recommended Relator be promoted to Institutional Healthcare Representative (IHR) (i.e. selling to institutions such as hospitals, not just to individual physicians or physician practices). The recommendation was based on Mr. Collins' performance matching Pfizer's "core values." Relator was promoted to IHR in July 2001. As an IHR, Relator was responsible for covering four major health systems consisting of many hospitals and about 20 outpatient clinics associated with them.

39. By December 2001, Relator was selected to train as the Assistant to the Southwest Regional Manager. By November 2002, Relator ranked as the seventh best sales representative in the Steere Division among all 84 institutional healthcare sales representatives nationally.

40. In August 2002, the illness of Relator's mother caused him to seek a transfer from Fort Worth, Texas to Provo, Utah. The only opening there was as a sales rep in the Pratt Division (to replace Corbett Carver who had been promoted to IHR in Salt Lake City). Relator changed Divisions and became part of the Pratt Sales Division. He took a demotion in title (to sales rep), but kept the same pay grade. Relator's new division was the leader in LIPITOR sales.

41. By October 1, 2002, Mr. Collins' transfer to Utah was complete and he began working in Utah's "Pilot District" where he was responsible for selling LIPITOR, NORVASC, ZYRTEC, ZITHROMAX and VIAGRA. His new District Manager ("DM") was Scott Latimer, who was the DM for the Labs Division and the "Cluster X" Utah Pilot Program, which included the "Cluster X" representatives and IHR's in the Salt Lake and Provo, Utah Territories. Mr. Latimer had been with Pfizer since February 1990, including over six years as a DM. For the

year ending December 2002, despite Relator's move to Utah and the attendant transitional time, Mr. Collins generated more than \$27 million in sales for Pfizer U.S. Pharmaceuticals.

42. Relator's compensation package, like that of other sales representatives, included salary, potential bonus(es), potential rewards trips, tuition reimbursement for anyone seeking advanced degrees, a handsome "ACE" Point Rewards compensation, health insurance for Relator and his family, other insurance benefits, and numerous other fringe benefits.

43. Mr. Collins, like other sales representatives, had a marketing budget. The size of a rep's budget depended on the size of their territory, and the type/level of sales representatives they were. For example, sales representatives had between \$28,000-\$35,000 per year for meals, travel, expenses, etc., and an additional \$8,500-\$10,000 per year to pay for speaker honoraria, preceptorships and the like. IHR's and other specialty reps (e.g., CHS reps, RU reps) had between \$45,000 and \$50,000 with an additional \$12,000 to \$15,000 or more per year to be used for "developing" residents and fellows to speak, as well as paying honoraria to staff and other trusted specialists to speak to residents and fellows to change their prescribing toward Pfizer products, or reinforce their commitment to write Pfizer products. This money was supplemented with additional funds each district manager "held back" at the first of the year and allotted to the reps or specialty reps who used their money in the first 8 or 9 months of the year in order to generate greater returns. Management also had budgets to be used separately, or to supplement, reps' budgets. For example, as illustrated below, District and Regional Managers had *annual* marketing budgets estimated by Relator to be about \$80,000 for DMs, \$100,000 for RMs, \$50,000-\$60,000 for RMRs, National Account Managers and National Healthcare Organization Representatives, and \$40,000-\$50,000 for PharmD Pharmacy Consultants ("CECs"). In addition, the Disease Management Teams had what appeared to be "limitless" budgets (hundreds

of millions of dollars/year). Pfizer expected to get a \$10 return on investment (i.e. sale of its drugs) for every \$1 spent through marketing budgets.

44. In addition to these cash budgets, Pfizer regularly provided the reps and the managers with very large volumes of drug samples that were to be liberally provided to customers to, *inter alia*, influence prescription writing habits and formulary choices. Described below are the volume of samples Relator had in Texas as a rep and an IHR and in Utah as a rep.

H. Summary of Facts and Allegations

45. As outlined in detail below, Pfizer has engaged in numerous types of illegal activity on a national scale involving the marketing, selling, prescribing, pricing, and billing of LIPITOR, VIAGRA, ZYRTEC, NORVASC, ZITHROMAX, ZOLOFT, GLUCOTROL XL and CADUET, and the pricing and promotion of numerous other drugs including without limitation DIFLUCAN, ARICEPT, TROVAN, CELEBREX, BEXTRA, RELPAX and DETROL LA. Among Pfizer's transgressions are the following:

(a) using unlawful advertising, including, without limitation, unapproved articles, price lists and other materials, including to promote off-label uses of the Drugs;

(b) providing unlawful incentives (i.e. kickbacks) to customers in exchange for patient referrals, prescribing of medications manufactured and/or sold by Defendant, and to facilitate the placement of such drugs on formularies; and

(c) engaging in various activities which affected the pricing of Pfizer's drugs and resulted in Government Health Care Programs overpaying for Pfizer's drugs, including without limitation, by distributing large numbers of drug samples to all clinics, doctors offices and health institutions, that were never reported to Government Health Care Programs; and

(d) Marketing the maximum dosages of the Drug, including in the off-label context and/or when not medically reasonable or necessary, and thereby increasing the risk of serious side effects and otherwise undermining the quality of care afforded to patients.

Moreover, Pfizer made false representations to the government in the context of the investigation and negotiation of the Neurontin settlement and has violated the terms of both Corporate Integrity Agreements (“CIAs”) it entered into with the United States Department of Health and Human Services OIG; and Pfizer retaliated against the Relator for his complaints about Pfizer’s illegal activity in violation of the federal False Claims Act and the CIAs.

46. Pfizer’s illegal activities are each violations of law, but together demonstrate a concerted national corporate strategy to use kickbacks, off-label promotion, pricing “incentives” and other tactics directed from the highest levels of the company to assure that Pfizer’s drugs would not only compete, but would receive preferential treatment, thereby putting Pfizer’s competitors at an unfair disadvantage, depriving certain providers and consumers of a fair and informed choice, and causing Government Health Care Programs to expend excessive amounts of money to reimburse the cost of Pfizer’s drugs. All of this has been done despite two CIAs, the OIG’s Pharma Guidelines, and internal complaints from employees such as Relator who instead of being treated with respect, are harassed and harshly retaliated against.

I. Specific Examples of Pfizer’s Illegal Activities

1. Pfizer’s Use of Illegal Price Lists in Violation of the FFDCA

47. By October 1, 2002, Mr. Collins’ transfer to the Utah “Pilot” District was complete. A few months earlier another co-worker, Bryan Osborn, began working at Pfizer in Utah’s Parke-Davis III Division within the Utah Pilot managed by District Manager Scott

Latimer. At about the same time Mr. Collins arrived in Utah, Mr. Osborn completed Pfizer training. Around the time of Relator's arrival, September 27, 2002, Mr. Osborn distributed to his co-workers by electronic mail ("e-mail") a price list that contained a direct cost comparison of Pfizer's drug ZYRTEC with its competitors as a way to help his new co-workers increase sales and meet quotas.

48. Every month all sales representatives with responsibility for sales of drugs in the same territory would have a meeting, known as a "LAT" to compare notes and make sure they were calling on all the physicians, and to be sure they were also focused on the most important physicians so their time was used most efficiently. The District Manager would typically attend such meetings.

49. At the Utah District "LAT" meeting on May 9, 2003 attended by his co-workers in the District and his District Manager, Mr. Osborn gave his co-workers handouts and suggestions on the use of homemade local comparative price lists for the drug LIPITOR based solely on prices at a local Wal-Mart ("the Wal-Mart Price List"). His original price list was highlighted (as were the copies) to compare the prices of LIPITOR 10 mg (\$66.08) with competing drugs Zocor 20 mg (\$127.32) and Pravachol 40 mg (\$127.84). He told how he had used such lists to convince physicians to write prescriptions for Pfizer drugs, including LIPITOR. That was when Mr. Collins learned for the first time that Mr. Osborn had been using such price lists in selling to physicians.

50. Relator was very concerned over what he saw as illegal price lists being used to sell to doctors. Immediately following this meeting, Mr. Collins approached his District Manager, Scott Latimer, in the meeting room, alone after everyone else had gone. He told his Manager words to the effect that Pfizer had good products and good sales reps and they could do

really well without doing anything that was wrong. Mr. Latimer spoke to Relator in words to the effect: "Don't worry about it Blair."

51. The next business day, May 12, 2003, DM Latimer traveled to Denver for a Regional Managers and District Managers meeting to be held from May 12-16, 2003. Part of the agenda for this meeting was to discuss Pfizer's 2002 CIA, the Sarbanes-Oxley Act, sexual harassment and wrongful termination, etc., and various other legal developments, as a result of which Pfizer's legal department had issued new training for all U.S. employees. At that meeting the RMs and DMs also planned for an upcoming "Point of Action" ("POA") meeting of all sales representatives to be held in Denver. A POA meeting is a three day meeting held three times a year for the sales force to receive information from management on how to sell the drugs in the field for next four months. In addition, there are three mid-POAs during the year, and a "kickoff" meeting at the beginning of the year.

52. On Wednesday May 21, 2003, the Relator met with his DM at his request to see how RMs and DMs wanted VIAGRA presented at the upcoming POA meeting in Denver. This POA was a meeting for all of Region 8 Cluster X and included Utah, Washington, Oregon, Montana, Idaho, New Mexico, Wyoming, Colorado, Kansas, Oklahoma and part of Arizona. DM Latimer had earlier chosen Relator for leadership of the VIAGRA Team and they were discussing VIAGRA strategy for the POA. Relator had an article he intended to use and wondered if he should just bring the original article or if he should also bring a copy of it with key points highlighted. This query by Relator prompted the DM to say words to the effect that he needed to be sure to send a message out to everyone in the district to make sure their [detailing] books were "cleaned up" for the upcoming POA. He said it would be bad to have unapproved pieces in the books.

53. Unlike a typical POA meeting, all Pfizer DMs, RMs, vice presidents of sales and senior vice presidents for Cluster “X” were expected to be present at the upcoming Denver POA meeting. By voicemail on Friday May 23, 2003, to his sales team, DM Latimer reminded his team: “Hi team, it’s Scott, hey, it’s 12, about 12:30 on Friday, hey, I just wanted to see if I could get you all to do me a favor. To prepare for this POA meeting next week, uh, if you could do me a favor and just make sure that your detail books are, um, you know, that you have them in one place, you’ve got the visual aids in place, and, I’m sure there’s nothing in there, but if there’s anything like, um, price sheets, spreadsheets, you know, unapproved clinicals, uh, make sure that we get those things cleaned up, and uh, get those things out of there. Again, I’m confident that, uh, we’ve been pretty clear on that in the past, but if there’s any question on that, uh, please, uh, make sure that’s cleaned up. So if you have any questions, give me a call.” (emphasis added).

54. “Detail books,” as referred to in DM Latimer’s voicemail, are books that each sales representative has in which they keep all the material they use to assist them in selling drugs to customers. “Detailing,” as understood by Relator, includes all oral and written material presented by a sales representative to a customer such as a physician or a hospital. Relator’s understanding was that in “detailing” a representative was to use only Pfizer approved materials.

55. On May 29, 2003, the third day of the POA meeting in Denver, Relator learned that the ZYRTEC sales representatives were using a homemade list of competing drugs and a comparison of which Health Maintenance Organizations approve which drugs to sell to doctors. DM Latimer had approved use of this list. At that same meeting, sales representative Bryan Osborn redistributed the Wal-Mart Price List for LIPITOR and its competitors that he had handed out at the May 9, 2003 LAT meeting. According to Osborn, DM Latimer had approved the Wal-Mart Price List also, and indeed was present when Osborn used it in selling to Dr.

Badger and other cardiologists. According to Osborn, the DM discussed the Wal-Mart Price List with the doctors, emphasizing the low cost of LIPITOR. Mr. Osborn claimed these discussions were effective in changing doctors' minds. At the same meeting, Renee Christensen also revealed that she had been detailing doctors with certain Intermountain Healthcare ("IHC") newsletters. While Pfizer had sent the reps a United Healthcare pricing comparison as part of the materials for this POA, Christensen, Carver and DM Latimer decided to use the IHC piece instead of the UHC material because IHC was more relevant to the Utah territory.

56. Federal law prohibits using stated prices to be the means of selling medication by pharmaceutical manufacturers except in certain circumstances. Pfizer had distributed price lists that were acceptable, but the homemade price lists of the kind being used in the Utah District are illegal. When price lists are permitted at all they must meet several requirements, including: (a) prices must be verified by independent, objective, "outside" (i.e. not the company) sources for accuracy; (b) the list cannot compare competitor's drugs side by side because this implies that all of the drugs have similar/comparable composition, effectiveness, side-effects and safety; (c) prices presented must be industry-wide, i.e., not based on one pharmacy in one city; and (d) so-called "homemade" price lists (i.e. put together by an employee, not the company) are forbidden under any circumstances.

2. Pfizer's Unlawful Off-label Marketing and Use of Unapproved Articles

57. As noted above, in 2004, Pfizer entered into a global settlement with the government including a criminal plea, a civil settlement and a CIA, involving the off-label marketing of the drug Neurontin which Pfizer had acquired when it purchased Warner Lambert/Parke-Davis in 2000. While Pfizer implied that this off-label marketing was unique to Neurontin (and a hold over from Warner Lambert), the truth is that *Pfizer* has marketed many

drugs “off-label” over the years as part of a concerted strategy. Pfizer’s off-label marketing includes, without limitation, drugs developed and marketed by Pfizer in the 1990’s such as ZOLOFT, ZITHROMAX and VIAGRA, as well as other drugs, most notably LIPITOR, which Pfizer was marketing for Warner Lambert from launch in 1997, and was still off-label marketing more than 3-4 years *after* purchasing Warner Lambert. Indeed, the off-label marketing of LIPITOR and other drugs described herein was blatantly occurring during the Neurontin investigation and settlement negotiations, and continued afterwards. As demonstrated below, off-label marketing was/is but one strategy used by Pfizer to undercut competitors and preserve or grow market share and revenues.

a. Off-label Marketing of LIPITOR, NORVASC, and CADUET

58. Pfizer acquired the cholesterol lowering drug LIPITOR when it purchased Warner Lambert in 2000. Before that, Pfizer sold Lipitor with and for Warner/Lambert starting in 1997 when Lipitor was launched. There were various competitors to LIPITOR, including Zocor (Sumvistatin), manufactured by Merck, and Pravachol (Pravastatin), manufactured by Bristol Myers Squibb.

59. Over the years after launch, one of LIPITOR’s main drawbacks or weaknesses versus its competitors was that there was no “outcomes data” for LIPITOR, i.e., data that showed that LIPITOR reduced morbidity and mortality. In contrast, by 1997, *both* Zocor and Pravachol had been FDA approved for “outcomes data” for a few years. In addition, Zocor and Pravachol were both approved/indicated to reduce cardiovascular events [i.e. strokes and heart attacks] in diabetic patients (of which there are now some 21 million in the U.S., increasing at about 16%/year since 1995) and in patients with atherosclerosis (i.e. hardening of the artery walls). However, from the time LIPITOR was launched in 1997, it had neither outcomes data

nor approval for use in diabetic or atherosclerotic patients.

60. Relator began selling Lipitor in October of 2000 while in the Southwest Region of Pfizer, and he continued selling Lipitor after he moved to Utah in October 2002. In Lipitor's first years on the market it enjoyed great success, growing at 12%-15%/year. However, in 2000, Merck began to promote Zocor using Merck's "Heart Protection Study", and by September 2001, LIPITOR sales began to go flat. This trend worsened with the FDA approval of Zetia (manufactured by Merck and Schering Plough) in 2002. As a result, during the period October 2001- October 2002, sales of Lipitor were flat and then falling, especially among specialists such as cardiologists and endocrinologists whom Pfizer viewed as critical thought/opinion leaders able to influence the prescription writing habits of primary care physicians. See the *Lipitor Lowdown*, Issue 1 January 2003 (a newsletter distributed to Cluster X employees). Similarly, according to that issue of the *Lipitor Lowdown*, Lipitor monthly detail share [i.e. sales calls by reps] and monthly sample share [i.e. number of samples of the drug left with customers such as doctors, etc.] had both declined during the period September 2001- September 2002. In the newsletter, Pfizer headquarters called on reps and managers to increase both details and samples because each is a "key driver that influence physician prescriptions." (*Id.* p. 7, emphasis added).

61. In addition to flat or falling LIPITOR revenues, by early 2003 Pfizer was anticipating *three* new competitors to Lipitor. One of them, Zetia, manufactured by Merck/Schering Plough and approved in October 2002 was the first cholesterol lowering drug to work through the small intestine. Zetia is also mentioned in the *Lipitor Lowdown*, *supra*. The two other looming competitors were Crestor, manufactured by Astra-Zeneca and to be marketed using members of the former Warner Lambert Lipitor Disease Management Team who had launched Lipitor (Crestor was ultimately approved for marketing on or about August 12-13,

2003); and Vytorin (a combination of Zocor and Zetia that would compete with CADUET—also noted in the *Lipitor Lowdown*), ultimately approved in October of 2003.

62. Through the POA meetings in 2003, Pfizer headquarters directed a national strategy to turnaround Lipitor's performance and blunt the competition. For example, as described in detail below, the materials and slides developed by Pfizer for the August 2003 mid POA state Pfizer's clear concern that: "this is the most important time in the [Lipitor] brand's history since it was launched in 1997;" "[in] June 2003, LIPITOR owns its smallest percentage ever of the cholesterol market and is losing market share and this trend must be reversed;" and "the months of August to November 2003 will be 'three critical months' for LIPITOR."

63. Among the company's objectives were to "Take ownership of *specific patient types*" (emphasis added), namely, diabetics, atherosclerotic, and hypertensive patients. The slides outline the ways to do this, essentially through incentives/kickbacks and through off-label marketing. Key to this strategy is Pfizer's plan to use "Exciting New Data on the Horizon for LIPITOR," i.e. studies that address these targeted "specific patient types," including:

"ASCOT" which "studies the effect of lipid-lowering in the hypertensive patient"

"CARDS" which "studies the effect of lipid-lowering in the diabetic patient" and

"REVERSAL" which "studies the effect of lipid-lowering on the progression of atherosclerosis." (sic) (emphases added).

However, at that time, none of these studies should have been used in any detailing by the sales force to physicians or other customers. Pfizer didn't receive approval to change the labeling of LIPITOR to include outcomes data or a statistically significant cardiovascular benefit for the hypertensive patient until late July-early August 2004, almost one year after this 2003 mid POA. The CARDS trial was not submitted to the FDA until October 2004, and *still has not been approved* by the FDA for a revision in LIPITOR's package labeling for the prevention or

reduction of cardiac events in the diabetic patient. The REVERSAL study, with Pfizer's claim that LIPITOR can reverse the effects of *atherosclerosis*, has to Relator's knowledge, not been submitted to the FDA; and it has never been approved for Lipitor's package labeling. In other words:

- from at least mid-2003-mid 2004, Pfizer used the results of the ASCOT study to engage in unfair competition and misleading and off-label marketing of LIPITOR for the treatment of hypertensive [i.e. high blood pressure] patients who had normal cholesterol levels, *and* to tout "outcomes data" [i.e. mortality and morbidity] for LIPITOR; and
- since at least mid-2003 and continuing at present, Pfizer has used the CARDS and REVERSAL studies to engage in off-label marketing of LIPITOR for treatment of diabetic and atherosclerotic patients, in both cases claiming that LIPITOR reduces the number of cardiovascular events [i.e. heart attacks and strokes] in such patients.

64. Pfizer's 2003 Lipitor marketing strategy (described in detail below, combining off-label marketing with kickbacks and other incentives including heavy sampling), was extremely successful. By the end of 2003, there was an impressive turnaround in LIPITOR revenue: despite the launch of two new competitors (Vytorin and Crestor) into the market and the dismal first 6-8 months of the year, LIPITOR revenue rose by 18% for 2003. The upward trend continued into 2004-2005.

65. In the first quarter of 2004 (compared to the first quarter of 2003), LIPITOR revenues rose by 17% (or \$510 million) (see SEC filing April, 2004), with CEO McKinnell declaring that this increase was due to "reinforcing data from the ASCOT, CARDS, REVERSAL

and PROVE-IT studies, *which have all demonstrated early and significant improvement in cardiovascular outcomes.*" (emphasis added). By the end of 2004, LIPITOR (and NORVASC and CADUET) were on over 80% of the national formularies. In its January 15, 2005 8-K filing with the SEC for the last quarter of 2004, Pfizer states: "The performance of LIPITOR is driven by the wealth of clinical evidence from such trials as ASCOT-LLA, REVERSAL, CARDS and PROVE-IT which are shaping cholesterol management." Statement of Karen Katen, Executive Vice President of Pfizer Inc. and President of Pfizer Global Pharmaceuticals. See January 15, 2005 8-K filing with the SEC for the last quarter of 2004. See also Pfizer's 2004 10-K filing in which Ms. Katen and the Pfizer CEO Hank McKinnell both explain the connection between LIPITOR'S impressive revenue growth and these *off-label* studies.

66. LIPITOR revenues continued to rise in 2005, with the first quarter of that year recording revenue of over \$3 billion, resulting from another substantial gain (i.e. about 20%) compared to the same period in 2004. During 2005, in addition to ASCOT, CARDS and REVERSAL, Pfizer touted other studies as well including PROVE-IT and Treat to New Targets ("TNT") released in March 2005 (although TNT did not cover diabetic or AT patients either). According to Pfizer's SEC 8-K filing dated April 19, 2005, TNT found that intensive therapy with Lipitor 80 mg can reduce cholesterol and cardiovascular events to among the lowest levels ever achieved in the history of statin trials, *with a safety profile comparable to that of lower-dose LIPITOR therapy.* At least the latter claim is patently false: according to the LIPITOR approved package insert, the incidence of irreversible liver damage jumps from 0.2% with LIPITOR at 10 or 20 mg. to 2.3% at 80 mg. In other words, with some 65 million people or so taking LIPITOR in the United States, that is a difference of some 130,000 patients (.2%) developing rhabdomyolysis (irreversible liver damage) versus some 1,495,000 patients (2.3%) developing

this condition. Nevertheless, according to CEO McKinnell, “These results take the treatment of cholesterol to new frontiers, while also reinforcing data from the ASCOT, CARDS, PROVE-IT, and REVERSAL studies—which have all demonstrated early and significant improvement in cardiovascular outcomes.”

67. Using the TNT trial to sell LIPITOR constituted (and still constitutes in some aspects) illegal off-label marketing. In particular, from 2005 until at least May 2007 when the FDA approved a change in the LIPITOR label for five new indications (listed above in paragraph 22), it was illegal to use TNT to promote those five new indications. Continuing to this day, it is illegal to use TNT to promote the use of LIPITOR for diabetics and/or AT patients. It is also illegal to use it to advocate that 80 mg of LIPITOR provides a greater benefit to the patient than 10 mg of LIPITOR *with the same level of side effects* constitutes off-label marketing. In fact, the results of the study itself did not show that LIPITOR 80 mg had the same level of side effects as LIPITOR 10 mg, and neither does LIPITOR’s package labeling, as most recently approved by the FDA in May 2007.

68. The first of the three studies Pfizer used as the foundation for its 2003 off-label marketing campaign to aid Lipitor’s spectacular turnaround was The Anglo-Scandinavian Cardiac Outcomes Trial (“ASCOT”). This study consisted of a parent study, and a substudy known as the ASCOT Lipid Lowering Arm (“LLA”), which together studied the effect of lipid lowering in some 22,000 patients with *hypertension (i.e. high blood pressure), but normal cholesterol ranges*. One part of the study consisted of about 8,000 patients and compared those who were treated with an ACE Inhibitor alone with those patients who were treated with an ACE Inhibitor *and* NORVASC. Another part of the study, ASCOT LLA, involved some 12,000 patients whose cholesterol ranges were normal, and compared patients in one group who were

treated with an ACE Inhibitor and no LIPITOR with patients in another group who received LIPITOR *and* NORVASC. ASCOT also studied/contained “outcomes data” for LIPITOR. The study showed that those patients who were treated with LIPITOR had fewer heart attacks and strokes than the control group who was not treated with LIPITOR. The ASCOT study was slated to last five years, but it was ultimately stopped ahead of schedule because the data showed positive effects on hypertension from NORVASC when used in combination with an ACE Inhibitor; and because the ASCOT LLA data showed positive effects of LIPITOR on hypertension. The ASCOT data also purported to show that those patients who were treated with LIPITOR had fewer heart attacks and strokes than the control group who was not treated with LIPITOR (in other words, it provided positive “outcomes data”).

69. The second of the three studies Pfizer used in 2003 was the “CARDS” study. This study consisted of only about 2,200 Type 2 *diabetic* patients who had normal cholesterol levels; about 84% of them had high blood pressure. The study compared those being treated with a 10 mg. dose of LIPITOR to those on placebo (i.e. no statin drug at all) to see what, if any, effect there would be on cardiovascular events, i.e. heart attacks and strokes. Of the 2,200 patients, 600 ended up not being evaluated in the study results.

70. Pfizer also stopped the CARDS study early, not because it showed that diabetic patients receiving LIPITOR had fewer cardiac events than those receiving no statin at all, but because Pfizer wanted to use ASCOT to market LIPITOR as a way to eliminate angioplasty procedures in diabetic patients. Consequently, Pfizer claimed that CARDS (even with its small population and lack of data) showed the same benefit for the diabetic patient that ASCOT had shown for the hypertensive patient. Pfizer also fostered the false impression that a 40 or 80 mg. dose of LIPITOR would prevent cardiovascular events in diabetic patients (even though CARDS

patients only received a 10 mg. dose of Lipitor). In fact, diabetic patients are at a much greater risk of heart attack or stroke than a hypertensive patient, and bypass surgery or angioplasty are the traditionally accepted therapy for cardiac patients who suffer from diabetes. Using LIPITOR for the treatment of such at-risk patients effectively leaves these diabetic patients untreated. Moreover, diabetic patients are at higher risk for liver damage from LIPITOR.

71. The third study Pfizer touted was “REVERSAL.” This study consisted of only about 502 patients with *atherosclerosis* [hardening of the arteries] who had normal blood pressure (unlike the ASCOT patients) and slightly elevated cholesterol levels (unlike the ASCOT patients). REVERSAL was intended to study the effect of using LIPITOR on the progression of atherosclerosis. The study was completed by September 2003, and Pfizer, again using the momentum from ASCOT, claimed that REVERSAL, despite its small patient population, showed LIPITOR’s ability to reduce cardiovascular events in the atherosclerotic patient. In fact, REVERSAL merely showed that in the 136 patients who were treated with LIPITOR vs. the 147 patients who were *not* treated with LIPITOR (17 patients did not continue with the study and were not evaluated), those patients treated with LIPITOR had a *slight* reduction of plaque in the artery wall based on ultra sound evaluation. In other words, REVERSAL did *not* show a reduction in any cardiovascular events for these atherosclerotic patients, but merely a slight reduction of plaque in the artery wall that was evaluated.

72. As noted above, from at least mid-2003 to mid 2004, Pfizer used the results of the ASCOT study to engage in off-label marketing of LIPITOR for the treatment of hypertensive [i.e. high blood pressure] patients who had normal cholesterol levels, and to tout “outcomes data” [i.e. mortality and morbidity] for LIPITOR. In late July-early August 2004, the FDA approved such use of LIPITOR, but in the interim period, Pfizer engaged in unfair competition

and misleading and off-label marketing.

73. In addition, since at least mid-July 2003 and continuing to date, Pfizer has used the CARDS and REVERSAL studies to engage in off-label marketing of LIPITOR for treatment of diabetics and atherosclerotic patients, respectively, in both cases claiming that LIPITOR reduces the number of heart attacks and strokes in such patients. Significantly, the FDA has not approved such additional indication for LIPITOR's package labeling, nor has the FDA approved LIPITOR for the prevention or reduction of cardiac events in the diabetic patient (based on CARDS or any other study), even though Pfizer submitted the CARDS study to the FDA in October 2004. As noted above, using LIPITOR for the treatment of such at risk patients effectively leaves them untreated, and increases their risk of liver damage.

74. At least as of July 2007, Pfizer has not obtained from the FDA a revision in the package labeling for LIPITOR based on the REVERSAL study. Thus, LIPITOR is not indicated for the prevention or reduction of cardiovascular events (i.e. heart attacks or strokes) in atherosclerotic patients. Rather, the FDA approved treatment for an atherosclerotic patient continues to be angioplasty because the arteries are so clogged and the benefit is so urgently needed to allow blood flow back to the heart.

75. It is difficult to imagine the FDA approving such an indication for LIPITOR in the diabetic or atherosclerotic patient at this time given: the severe consequences of failing to appropriately treat diabetic and atherosclerotic patients; the small numbers of patients (2200 and 502, respectively) in the CARDS and REVERSAL studies (vs. 22,000 patients in ASCOT); and the shorter time of the CARDS and REVERSAL studies (2 years and 18 months, respectively vs. 3.3 years with ASCOT).

76. The steps taken by Pfizer to implement its off-label strategy for LIPITOR

beginning in the first quarter of 2003 are detailed below. As described later in this Complaint, Pfizer combined this off-label campaign with kickbacks and various other illegal incentives. These efforts proved extremely effective, successful, and lucrative.

77. Pfizer's off-label marketing strategy for Lipitor came from the highest levels of Pfizer. Relator's exposure to Pfizer's off-label marketing campaign for LIPITOR began in earnest in March 2003. By e-mail on March 26, 2003, John Woychick, the Senior Vice President of Sales for Pfizer Pharmaceutical's Cluster X, informed all of the Regional and District Managers as well as Rick Burch, Senior Vice President over Cluster A, and Mick Mosebrook, Senior VP of Sales of US Pharmaceuticals, about the status of ASCOT, and what use the sales force could (or could not) make of this study. In particular, he informed them that the results of the lipid-lowering arm of the trial (ASCOT LLA involving LIPITOR) would be reported at the upcoming American College of Cardiology ("ACC") meeting on April 2, 2003, and shortly thereafter the full results of ASCOT would be published in a major medical journal. *The antihypertensive arm of ASCOT, which included treatment with Pfizer's NORVASC, was still ongoing, and would not be reported at the ACC.* He noted that ASCOT would show "many benefits of treatment with LIPITOR, the most exciting aspect of ASCOT is that it is expected to provide extremely compelling morbidity and mortality data for LIPITOR." [i.e. outcomes data]. He cautioned, however, that:

"While ASCOT results will provide important news about LIPITOR, it is critical to remember that you will ***not be allowed to discuss*** the specific results of ASCOT with physicians or customers for two very important reasons: 1. The results are outside the currently approved labeling for LIPITOR. 2. *The results of the trial will potentially be used in an FDA filing that may change the labeling of LIPITOR. Any discussion of the ASCOT results could place the future labeling of LIPITOR in jeopardy.* It is important to remember that Medical Information Services is your best resource for physicians or customers who have specific questions about ASCOT." (italics emphasis added).

78. Despite this caution, the email from Woychick stated that representatives would

be provided with “a number of relevant materials and field resources, which will include:

ASCOT Design/Results Backgrounder (4/23/2003; via email);

ASCOT Results Reprint (to be distributed via Washington Legal Foundation [WLF] Principles) (week of 4/7/2003);

‘All about ASCOT’ Training Module (mid-end of April).” (emphasis added).

Woychick went on to say that “For your information, attached to this e-mail please find an “ASCOT Study Design Backgrounder” that provides a summary of the overall design and objectives of the trial. Woychick concluded the email by reminding all that it is critical to stay “focused on our POA 1 strategies [from January 2003—see *Lipitor Lowdown, supra*]: delivering a consistent and targeted *Power you can trust*™ message, increasing our market share with specialists and taking ownership of specific dyslipidemic patient types.” In other words, they were going to target patients like those ASCOT patients whose cholesterol levels have been considered normal in the past, and whose blood pressure ranged from elevated to high--meaning a range from 125 over 85: 125/85 to 150 over 100: 150/100. Thus, despite the cautionary email, Pfizer distributed marketing material in breach of 21 U.S.C. section 360aaa.

79. Later that same day, District Manager Latimer forwarded Mr. Woychick’s email to the Utah District sales force, including the Relator, with the following message: “Please read John Woychick’s message regarding ASCOT. As you can see we will be unable to discuss this study. The best way to get this information to your physicians after its release is Medical Information (solicited by physician) or the WLF [Washington Legal Foundation] that will be available on April 7.”

80. On April 5, 2003 The LANCET published the ASCOT study/results. The primary significance of the study for Pfizer was that it finally provided “outcomes data” for LIPITOR, i.e.

data on mortality and morbidity. This had not previously been available for LIPITOR, although competitor reps who sold drugs such as Zocor and Pravachol had approved studies they could present to doctors. ASCOT provided scientific data to support a claim that LIPITOR was an effective treatment for patients whose blood pressure indicated a significant risk factor for a heart attack, but who did not have a cholesterol problem. When the study was published, and at the time that Woychick sent his email providing details of the ASCOT study, the prescription of LIPITOR for those “not conventionally deemed dyslipidemic” (i.e. those without a cholesterol problem) was off-label.

81. Pfizer’s reprint of The LANCET article (provided in multiple copies to its sales force) contained a cover sheet put out by Pfizer which specifically noted that LIPITOR was *not* indicated for prevention of cardiovascular events. Nevertheless, as discussed below, Pfizer went on to instruct its sales force to promote Lipitor for these purposes off-label. This followed a standard practice at Pfizer. For example, in April 2003 Pfizer also published and distributed to its sales force a “do not detail” piece regarding a study on C - reactive protein (“CRP”) in the New England Journal of Medicine in November 2002 (on whether CRP is an indicator of cardiovascular events). While on its face instructing the sales force not to discuss CRP with doctors, to refer any questions about it from doctors to medical affairs, and that Lipitor is not indicated for reducing CRP, the 8 page glossy handout from Pfizer headquarters provides the sales reps with great detail on the study and how it fits with Lipitor’s marketing message and strategy. As with other so-called “do not detail” pieces sales reps like Mr. Collins received in the mail prior to a POA, the reps would use a paper cutter supplied by their DM to cut off the bottom of the glossy handout where it said “do not detail” and then put the copies in their detail binders.

82. Based on his experience at Pfizer, Relator believed he was allowed to discuss the

ASCOT study, just as he had been allowed to detail other studies such as the ALLHAT study with NORVASC earlier that year. In particular, he understood that he was allowed to discuss the parameters of the study with doctors/customers and then point to the general area of the page where the results of ASCOT were with a pen, without discussing them. On May 9, 2003, before a LAT meeting with his sales group, Relator told his DM how he was detailing the ASCOT study; his DM corrected him and told him he was not allowed to point to the results with his pen.

83. However, at the LAT meeting, a senior sales representative, John Dehaas, a then seventeen year Pfizer employee, showed the group how he was detailing the ASCOT study—and it was exactly how Relator had been doing it, and exactly how they had been detailing ALLHAT for NORVASC before. Neither Relator, nor more importantly the DM, corrected Dehaas, nor was Relator or Dehaas told that by presenting the study results *or reprints* to a doctor he was engaging in illegal off-label marketing using a clinical study. On information and belief, other sales representatives were also presenting the study to doctors for the off-label use while not “discuss[ing] the specific results” of the study.

84. Indeed, despite the Relator’s May 9 discussion with the DM, at the LAT meeting in Provo, Utah, or again at the POA 2 meeting in Denver, Colorado on May 27-29, 2003, which was attended by Woychick, the sales representatives, including Relator, were presented with a “LIPITOR POA 2 PLAYCARD.” A Playcard generally is a laminated Pfizer “cheat sheet” on how to promote a particular drug. A Playcard is developed by RMs and the Vice President of a Sales Division under which the drug is marketed (in this case, Dan Collier, VP of the Pratt Division). This information would then be disseminated to the specialty and field sales representatives at their next POA (identified on the “playcard” as “POA 1 – POA 2 - or POA 3) so that for the upcoming quarter all Pfizer representatives would give a consistent message to all

of the doctors across the country. In the case of the LIPITOR Playcard, the design was to use the favorable results from ASCOT to boost sales of LIPITOR. The card contains quotes on what the representatives should say to doctors, including one that reads:

“Doctor, as you know competitors have been detailing that we haven’t had ‘outcomes’ data, in the past. We now have a newly published trial, the ASCOT, are you familiar (Detail study and patient type if not familiar).” (emphasis in original).

85. In other words, the sales representatives were being instructed that they should affirmatively discuss or “detail” this study with the doctors, rather than waiting for a doctor’s inquiry and then referring such inquiry to Pfizer’s Medical Information Services. In addition to the Playcard, the sales representatives at the POA meeting were trained on ASCOT both at the POA, and leading up to it. They had received training modules on ASCOT for 6 weeks leading up to the POA. Thus, though they supposedly were not supposed to discuss the study results, all the sales representatives were well versed in ASCOT.

86. “Playcards” like the one distributed for LIPITOR, were distributed three times per year at POA meetings; typically there is one Playcard/POA. The normal approval chain before a Playcard would be distributed would be that the Vice President of a Sales Division, in this case, Dan Collier who was Vice President of the Pratt Division under which LIPITOR was marketed, would meet with Regional Managers to decide what information could be used. At a Regional Manager/District Manager meeting, like the one in Denver May 12-16, 2003, there would then be a decision on what material was most effective, i.e. would help the drug sell best. After that, the Playcard would be drawn up and distributed to the sales force at a POA.

87. The sales force began using doctors to speak about ASCOT as early as May 2003. For example, Bryan Osborn arranged a program at which Eliot A. Brinton, M.D. (who was Chief

of the Section of Metabolism, Endocrinology and Nutrition at the Carl T. Hayden VA Medical Center and an Associate Professor at the University College of Medicine) spoke on or about May 20, 2003 to a group of other doctors in Orem, Utah. In emails to Dr. Brinton, Mr. Osborn noted that he would bring copies of ASCOT for the participants and explained the purpose of the program as follows: "I am very grateful that you will be speaking for us on Tuesday. I am presenting this topic to the other physicians as an opportunity to discuss the recent ASCOT lipid lowering arm trial with you and also to give these physicians an opportunity to ask you for some advice on how to effectively treat the metabolic syndrome patient. *The emphasis on this presentation will hopefully benefit Lipitor and its effectiveness.* Please let me know if you need anything from me. Thank you." Relator, his DM, Osborn and Dehaas attended this program. Osborn scheduled the speaker, "prepped" him, and brought all of the ASCOT articles to be handed out. The DM and Dehaas were there to observe, and to evaluate the speaker and Pfizer's relationships with the key physicians.

88. After the May 27-29, 2003 POA meeting, another e-mail was circulated regarding yet another study on LIPITOR, this one known as CARDS. Relator received this e-mail as well. The e-mail was from Dan Collier, Pfizer Vice President of the Pratt Sales Division within Cluster X, and the format is nearly identical to the earlier Woychick e-mail about the ASCOT study. The Collier email describes the status of the study, how helpful the results are for LIPITOR, and warns that the sales force is not allowed to discuss details about the trial with physicians or customers for the same reasons Woychick cited. Again it refers to Pfizer's Medical Information Services as the best resource for doctors or customers who have specific questions about CARDS and says questions should be referred there. Nevertheless, it too attached a "backgrounder," promised to forward additional information, and reminded the sales force to stay focused on the

POA-2 strategies: “consistently deliver a complete *Power you can trust*TM message, increase our market share with specialists ...take ownership of specific dyslipidemic patient types.” The e-mail is signed “The US LIPITOR Team.” It appears that Woychick’s email on ASCOT and Collier’s email on CARDS are derived from a common template email and indicates a corporate *modus operandi* regarding new unapproved uses of its drugs.

89. The results of the third LIPITOR study at issue here, REVERSAL, were talked about in Pfizer beginning by at least early summer 2003 (although the study results were not officially released/published until September 2003). Also, by forwarding a voicemail from Bryan Osborn to his sales team, including Relator, on July 9, 2003, District Manager Latimer informed them about a new Newsweek article on cholesterol drugs which mentioned LIPITOR and its potential off-label uses for treating Alzheimer’s disease and Multiple Sclerosis.

90. As already noted, the timing of the CARDS, ASCOT and REVERSAL studies/ results was critical to Pfizer and sales of LIPITOR: revenues from Lipitor in April-June 2003 were continuing the flat or downward trend that had started in 2001. Competitors Zetia and Zocor continued to be a challenge for LIPITOR, and two new competitors were on the horizon: a Zetia/Zocor combination (now known as Vytorin which at a lesser dosage lowers LDL as well as 80 mg. of LIPITOR), and, more significantly, Crestor (which could lower LDL—bad cholesterol— and raise HDL—the good cholesterol—almost twice as much as LIPITOR at every dose). Pfizer was especially concerned about Crestor not only because of its efficacy at lower doses, but because (a) the United States launch of Crestor was being done by Astra Zeneca using most of the former Warner Lambert (“WL”) LIPITOR Disease Management Team who had